Author's response to reviews

Title: Acceptability of self-collection sampling for HPV-DNA testing in low-resource settings: a mixed methods approach

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Version: 3
Date: 22 April 2014

Author's response to reviews: see over
April 22, 2014

The Editors,
BMC Public Health.

Dear Editors,

We appreciate the opportunity to resubmit our manuscript for consideration in *BMC Public Health*. All comments by reviewers have been addressed, with corresponding changes made directly to the manuscript where appropriate. Accompanying this letter, please find a revised version of our manuscript. Detailed responses to the reviewers are included below. Please let us know if there are any additional points we must clarify.

Thank you for your consideration of our manuscript. We look forward to hearing from you at your earliest convenience.

Sincerely,

Pooja Bansil

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Reviewer: Stephen E Hawes

Major Compulsory Revisions

1. Table 2: Numbers throughout the Table do not seem correct. For example, with regards to the first category “Concerns about taking self vaginal sample”, despite women being allowed to answer more than one category (plus having the “no_concern” category), the totals of “All Sites” sum to 3351, despite have a total sample size of 3461. Further, the percentages add up to less than 100% (they should be 100% if subjects could only provide one answer, >100% if they could provide >1 answer. Perhaps there is missing data which is not accounted for? Regardless, the percentages should sum to 100% of the non-missing data. Nicaragua is one source of a problem as the numbers sum to the correct total (704) but the percentages only sum to about 80%.

Please note that the categories presented in this part of the table are not mutually exclusive and that women were able to “check all that apply”. As a result, one cannot expect the number or the percentages in the column for each country to add up. Indeed there is missing data as some women did not answer the question at all.

2. In the next section of Table 2, the percentage for Neutral for Nicaragua is incorrect. It should be 7.5%, not 4.1%. Again, percentages for Nicaragua sum up to less than 100%.

This has been corrected.

3. Table 3. It would be best to reorder the Aids needed, so that “None” is either first or last in the list so that it is clear that it is an option. Again in this table, percentages do not sum to 100% and it is unclear if there is missing data. It appears that for Uttar Pradesh the totals sum to 925 but the overall sample size is 942.

Table 3 response categories have been reordered. Again, as stated above, the categories presented in this part of the table are not mutually exclusive and that women were able to “check all that apply”. As a result, one cannot expect the number or the percentages in the column for each country to add up. Indeed there is missing data as some women did not answer the question at all.

Minor Essential Revisions

1. Throughout Tables 2 and 3, p-values are provided which show that for each factor assessed, differences occur across the 4 study sites, all of which are significant at the p<0.001 level. However, the discussion and results are generally presented as if the findings are universal. Clearly, strategies to improve uptake or to quell worries will need to be specific to the cultural setting. For example, pictures might be useful in India but were less so in Uganda, and dolls might be useful in Uganda but not in Nicaragua.

This is true and to illustrate this point, we have inserted “culturally appropriate” to the following sentence in the discussion: “In a future study or during field implementation, we would recommend developing additional, culturally appropriate, education aids…”
2. Figure 2. Precision should be the same throughout the figure. 10 presumably should be 10.0.

This has been corrected in both Figure 1 and 2.

*Discretionary Revisions*

1. Abstract – It is unclear until the complete manuscript is read what the comparison group/alternative is with regards to the statement “Most surveyed women preferred self-sampling”.

We understand it may be confusing as written in the abstract until the entire manuscript has been read, but this is the only way for us to distinguish between women who completed the exit surveys from those that participate in semi structured interviews or FGDs.

2. Background – p5. The authors state that “correlation between self-collected and provider-collected samples is good” and also that one study found “a very high agreement (92%) between self- and provider-collected samples”. It is unclear if a distinction between correlation and agreement is attempting to be made. As is, it seems that correlation is only good but agreement is very high. These seem to be addressing the same concept but for some reason are being distinguished here.

We have unified these two sentences together because they are indeed addressing the same concept.

3. Background – p5. …”no studies have provided a more comprehensive and in-depth….”. More comprehensive than what?

We have changed the word comprehensive to “broad” to clarify that this study was unique in that it utilized and synthesized data from a variety of sources.

4. Especially in the discussion, but throughout the manuscript, it is unclear to me why self-collected sampling might be useful/cost effective if many women desire staff help, prefer having the sample collected in a health care facility, or require provider education. This is especially unclear in setting of a potential one-time screen as suggested on p13.

The setting of a one-time screen was suggested as an ideal/ hypothetical setting. Even though women would prefer to have staff help and/or collect the sample in a clinic, the time and resources needed for self-sampling are still less than as compared to other cervical cancer screening methods--thus being more cost effective in the long run.

Reviewer: Lindley Barbee

*Major Compulsory Revisions:*

DISCUSSION
1. The major conclusion that the authors draw from their findings is that 90% of women in these three countries found self-sampling to be acceptable. This is an overstatement of the findings. Although 90% women who completed exit interviews completed a vaginal self-sample, on the whole, the data from this study do not suggest that 90% of women find this acceptable. In fact, in Table 2, in the aggregate, 77.5% preferred self-sampling. And, in certain populations, i.e. Nicaragua, self-sampling was not acceptable to 50% of women. In addition, since the women had already agreed to participate in a study on cervical cancer screening, and if a proper informed consent was done they would have known self-sampling was part of the procedures, then the true measure of acceptability, in these terms, would be the number of women who agreed to participate in the study from all invited. Please qualify these findings.

We agree that 90% of the women that provided a self-collected vaginal sample does not equate to self-sampling acceptability. We have therefore rephrased and revised this finding in both the discussion and abstract.

Discretionary Revisions:
INTRODUCTION:
1. In the second paragraph, the authors state that CareHPV is cost-effective because has a “lower cost per test”. Compared to what? To other HPV tests? Please explain.

We have added “as compared to other HPV-DNA tests” to this sentence to help clarify our point.

2. Paragraph 3: the authors state that self-collected vaginal HPV tests are “10-19%” less sensitive than provider collected specimens – that could mean either 65 – 90% sensitive, or 74 – 81% sensitive. Suggest rephrasing.

We have rephrased this sentence for clarity.

3. suggest using “speculum” exam, or “speculum based pap smear” instead of “pap smear procedure”. Technically Pap smear refers to the pathologic review of cytology.

Revised as suggested.

4. verb tense changes. Consider revising

We have revised so that the verb tense is consistent.

5. Paragraph 4: Five studies is more than a “few”. Suggest using a different descriptor.

As suggested, we have changed “few” to “several”.

6. Paragraph 4, second line: the word “more” suggests comparison, but unclear what is being compared.
We have deleted the word “more” and re-worded this sentence.

7. The first objective, which is actually two, is confusing as written. Consider making two separate objectives.

As suggested, we have split the first objective in two objectives.

METHODS:

1. Since the manuscript describing the parent demonstration project is not yet published, suggest the authors provide more detail in the methods about its study design, objectives etc. As part of that description, strongly suggest a more detailed explanation of the collecting brush that women used for self-sampling, and the instructions that were given to women on how to collect the sample. Was there a visual educational tool? If so, consider adding that as a figure.

As the parent demonstration study has been published- we do not wish to add additional and/or redundant detail about the study design and methodology to this manuscript. We have updated the reference for the study.

2. Suggest using subheadings both in methods and results to organize the sections.

Subheadings have been added to the methods to distinguish between the quantitative and qualitative components of the study. We have also added subheading in the results to help organize the results into major themes/findings.

3. Please describe how the study population was selected. In the methods section it states that a 20% random sample was selected, but the description of the study population in the results makes it seem that it was by chance that there was a 20% response rate. Was 20% pre-specified and if women refused to participate, were more invited?

Yes- 20% was pre-specified and if women refused to participate, more women were invited. This has been noted in the methods section.

RESULTS:

1. Again, suggest subheadings to help organize this section. In particular, the manuscript moves from study population of the interviews/FGDs, directly to a paragraph on the surveys. But, the lead-in phrase calls them “exit interview sites” which is confusing with the interviews described above.

We have added subheadings to help organize this section. And have made some revisions so it is clear to distinguish between surveyed respondents and interviewed respondents.

DISCUSSION:
2. Why did self-sampling seem unacceptable to women in Nicaragua, whereas women in Uganda were happy to self-sample? Suggest the authors comment on these cultural differences in the discussion section.

*Unfortunately, we did not incorporate probing questions on why uptake of self-sampling may have differed across cultures. Since we do not have this data- we cannot comment on this in the discussion.*

3. Please expand on the limitation about the population chosen for the interviews and FGDs, as sampling from women who had to return for an abnormal pap results leads to a biased sample.

*This limitation has been expanded.*

Minor essential revisions

**BACKGROUND**

1. word “cost” prior to reference 2 should be “costs”

*Corrected*

2. Figures 1 and 2: please label with N study subjects in this part of the analysis, unclear which group of women is being presented.

*Revised Figure Titles to show the N study subjects and clarify which women are being presented.*